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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,371	04/30/2001	Keld Kaltoft	KALTOFT 1	2534

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,371	KALTOFT ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

6/9/04

1)☒ Responsive to communication(s) filed on *21 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40,60-83 and 85-90* is/are pending in the application.

4a) Of the above claim(s) *80-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40,60-79 and 85-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Applicant's supplemental response filed on 09/21/04

In view of the amendments , filed 06/09/04 and supplemental response filed, filed on 09/21/04 the following rejections remain

3. The following is a quotation of the second paragraph of 35 U.S.C. 112.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 40, 60-79 and 85-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40 and 61 are indefinite and ambiguous in the recitation of "disease associated cytotoxic T cell line". The characteristics and metes and bounds of "disease associated cytotoxic T cell line" are unclear and indefinite. It is unclear how to determine and what are the criterias for which T cell are associated with disease and which are not associated with disease. If Applicant means a cytotoxic T cells that were activated by a disease-specific antigen he should clearly stated this for clarity and consistence with the disclose of the specification.

It is noted that Applicant has amended claim 61 and deleted the word "normal" from the phrase " normal disease associated .... T cell". However, amended claims 40 and 61 still recited "a disease associated ...T cell".

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

6. Claims 40, 60-79 and 85-90 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,827,642 or by US Patent 6,316,257 for the for the same reasons set forth in the previous Office Action, mailed on 02/17/04

Applicant's arguments, filed 06/09/04 and 09/21/04 have been fully considered, but have not been found convincing.

Applicant asserts that: (i) total expansion of cytotoxic T cell which had achieved by US Patent '642 was only 30 PD. Similarly , total expansion of cytotoxic T cell which had achieved by US Patent '257 was only 27 PD. Thus none of cited references disclosed cytotoxic T cells that exceeded 40 PD as claimed in amended claims ; (ii) All cell lines provided in US Patent '257 are leukemic cell lines which are not derived from normal human (T) cell lines.

Contrary to Applicant's assertion, it is noted that US Patent '642 teaches a cytotoxic human T cells that were obtained and cultured by the same method using the same culturing condition as recited in the instant Specification. US Patent '642 teaches that disease-specific antigen activated T cells were incubated in the presence of the same factors that promote T cell growth as claimed (see column 9 in particular). US Patent '642 teaches that T cells were expanded in the presence of IL-2 and anti-cD3 (see column 13 in particular). US Patent '642 teaches that cytotoxic human T cells are also capable to enter a quiescent, non-dividing phase , remain viable and then be stimulated for further expansion (see column 13, lines 35-45 in particular).

Although US Patent '642 does not explicitly teaches that the obtained cytotoxic T cells have exceeded a life-span of at least 40, 50 or 60 PD or wherein the expected life span is at least 60,100, 150 or 200 PD as claimed said functional limitation would be inherent properties of the referenced cell composition, because said cytotoxic cells were obtained and cultured by the same method using the same growth conditions as claimed. Moreover, it is noted that the Specification disclosed that only two factors in the growth medium are minimum requirement to achieve at least 40 PD or unlimited growth (see pages 3, 5, 10-12 in particular). It is noted that the same two factors are present in the growth medium taught by US Patent '642. Since the office does not have a laboratory to test the reference cytotoxic T cells is applicant's burden to show that the reference cytotoxic T cells do not have the functional properties as claimed. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Similarly, US Patent '257 teaches a antigen-specific human cytotoxic T cell, that are obtained by rapid expansion method (see entire document, column 8 in particular). US Patent 257 teaches that culture medium comprising at least two growth factors including IL-2 ,, IL12, IL-7 (see columns 12 and 14 in particular). US Patent '257 teaches that cytotoxic human T cells are also capable to enter a quiescent, non-dividing phase , remain viable and then be stimulated for further expansion (see column 10 in particular). It is noted that the growth condition for expansion of cytotoxic T cells of the instant specification is the same as growth condition of US Patent '257.

With regards to the issue that "All cell lines provided in US Patent '257 are leukemic cell lines which are not derived from normal human (T) cell lines". The examiner disagrees with said statement. Applicant's attention is respectively drawn to column 7,linis 42-50, where it is explicitly stated that ' this invention provides a method for rapid producing large number of T cells, including human antigen-specific cytolytic and helper cells, isolated from an initial population of T cell". In other words, US Patent '257 teaches mammalian cells that are derived from normal human (T) cell lines.

Although US Patent '257 does not explicitly teaches that the obtained cytotoxic T cells have exceeded a life-span of at least 40, 50 or 60 PD or wherein the expected life span is at least 60,100, 150 or 200 PD as claimed said functional limitation would be inherent properties of the referenced cell composition, because said cytotoxic cells were obtained and cultured by the same method using the same growth conditions as claimed. Moreover, it is noted that the Specification disclosed that only two factors in the growth medium are minimum requirement to achieve at least 40 PD or unlimited growth (see pages 3, 5, 10-12 in particular). It is noted that the same two factors are present in the growth medium taught by US Patent '257. Since the office does not have a laboratory to test the reference cytotoxic T cells is applicant's burden to show that the reference cytotoxic T cells do not have the functional properties as claimed. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

The reference teaching anticipates the claimed invention.

6. Claims 40, 60-79 and 85-90 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,188,959 for the for the same reasons set forth in the previous Office Action, mailed on 02/17/04

Applicant's arguments, filed 9/25/00 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant asserts that total expansion of cytotoxic T cell which had achieved by US Patent '959 was only 23-26 PD thus cited reference does not disclosed cytotoxic T cells that exceeded 40 PD as claimed in amended claims.

Contrary to Applicant's assertion, it is noted that US Patent '952 teaches a cytotoxic human T cells that were obtained and cultured by the same method using the same culturing condition as recited in the instant Specification. US Patent '952 teaches that disease-specific antigen activated T cells were incubated in the presence of the same factors that promote T cell growth i.e. Il-2 and Il-4 and additional factors such as lectin or an antibody to Cd3 as claimed (see

columns 8, 9 and 18 in particular) . Although US Patent '952 does not explicitly teaches that the obtained cytotoxic T cells have exceeded a life-span of at least 40, 50 or 60 PD or wherein the expected life span is at least 60,100, 150 or 200 PD as claimed said functional limitation would be inherent properties of the referenced cell composition, because said cytotoxic cells were obtained and cultured by the same method using the same growth conditions as claimed. Moreover, it is noted that the Specification disclosed that only two factors in the growth medium are minimum requirement to achieve at least 40 PD or unlimited growth (see pages 3, 5, 10-12 in particular). It is noted that the same two factors are present in the growth medium taught by US Patent '959. Since the office does not have a laboratory to test the reference cytotoxic T cells is applicant's burden to show that the reference cytotoxic T cells do not have the functional properties as claimed. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

The reference teaching anticipates the claimed invention.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0850. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0851.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
March 2, 2005

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600